

1 UNITED STATES COURT OF APPEALS
2 FOR THE SECOND CIRCUIT
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5
6 August Term, 2003
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8 (Argued December 4, 2003 Decided October 18, 2004)
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10 Docket Nos. 02-9222, 02-9346
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14 GENEVA PHARMACEUTICALS TECHNOLOGY CORP.,
15 as successor in interest to Invamed, Inc.,
16

17 Plaintiff-Appellant,
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19 APOTHECON, INC.,
20

21 Consolidated-Plaintiff-Appellant,
22

23 v.
24

25 BARR LABORATORIES INC., BRANTFORD CHEMICALS INC.,
26 BERNARD C. SHERMAN, APOTEX HOLDINGS, INC., APOTEX, INC.,
27 SHERMAN DELAWARE, INC.,
28

29 Defendants-Appellees.
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32 Before:

33 CARDAMONE, SACK, and GIBSON*,
34 Circuit Judges.
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38 Plaintiffs manufacturers appeal an order of the United
39 States District Court for the Southern District of New York
40 (Sweet, J.) entered October 7, 2002 granting partial summary
41 judgment dismissing plaintiffs' claims that a competing
42 manufacturer and its supplier conspired to restrain trade and
43 monopolize the supply and retail markets of generic warfarin
44 sodium in violation of §§ 1 and 2 of the Sherman Antitrust Act
45 and § 7 of the Clayton Act.
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47 Affirmed, in part, reversed, in part, and remanded.
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51 * Honorable John R. Gibson, United States Court of Appeals for
52 the Eighth Circuit, sitting by designation.

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2
3 WAYNE A. CROSS, White & Case, New York, New York (Michael J.
4 Gallagher, Brendan G. Woodard, White & Case LLP, New York,
5 New York; Frederick R. Dettmer, Law Office of Frederick R.
6 Dettmer, New York, New York; David S. Preminger, Rosen,
7 Preminger & Bloom, New York, New York, of counsel), for
8 Plaintiff-Appellant Geneva Pharmaceuticals Technology Corp.
9

10 LOUIS M. SOLOMON, New York, New York (Harry Frischer, Colin A.
11 Underwood, Jennifer R. Scullion, Daniel J. Rothstein,
12 Proskauer Rose LLP, New York, New York, of counsel), for
13 Plaintiff-Appellant Apothecon, Inc.
14

15 MICHAEL J. GAERTNER, Chicago, Illinois (David G. Greene, Lord,
16 Bissell & Brook, Chicago, Illinois, of counsel), for
17 Defendants-Appellees Brantford Chemicals Inc., Bernard C.
18 Sherman, Apotex Holdings Inc., Apotex Inc., Sherman
19 Delaware, Inc.
20

21 KURT L. SCHULTZ, New York, New York (Alan B. Howard, Winston &
22 Strawn, New York, New York, of counsel), for Defendant-
23 Appellee Barr Laboratories, Inc.
24
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1 CARDAMONE, Circuit Judge:

2 This civil antitrust action was instituted by plaintiffs-
3 appellants Apothecon, Inc. and Geneva Pharmaceuticals Technology
4 Corp., which manufacture and distribute a generic form of
5 warfarin sodium, an anti-coagulant medication (a blood thinner).
6 The suit was brought under §§ 1 and 2 of the Sherman Antitrust
7 Act, 15 U.S.C. § 1 and § 2 (2000). Those sections make it
8 unlawful to enter into a contract, combination, or conspiracy in
9 restraint of trade (§ 1), and/or to engage in a conspiracy to
10 monopolize (§ 2). Plaintiffs' antitrust claims are based on the
11 alleged anti-competitive conduct of defendants-appellees Barr
12 Laboratories, Inc., a competing manufacturer of generic warfarin
13 sodium, and Brantford Chemicals, Inc., a supplier of clathrate,
14 which is the primary chemical ingredient used to make warfarin
15 sodium.

16 This litigation is about protecting the operation of our
17 competitive markets. Competition, which fosters innovation and
18 tends to lower prices for consumers, directly pits one producer
19 against another. When individual firms go head-to-head, one
20 might wish that the rules of the Marquis of Queensberry, which
21 ensure fair play,¹ would be uppermost in the competitors' minds.
22 The antitrust laws, however, safeguard consumers by protecting

¹ The code of rules that most directly influenced modern boxing was first published in 1867 under the sponsoring of John Sholto Douglas, Marquis of Queensberry (1844-1900), from whom they take their name. There are 12 rules in all, including "no wrestling or hugging allowed," to ensure a fair fight between contestants. See 7 Encyclopædia Britannica 870 (15th ed. 2002).

1 the competitive process. Those laws, unlike the Marquis of
2 Queensberry rules, are not designed to protect competitors from
3 one another's conduct.

4 Plaintiffs appeal from an order of the United States
5 District Court for the Southern District of New York (Sweet, J.),
6 entered October 7, 2002, which granted partial summary judgment
7 to defendants dismissing plaintiffs' antitrust causes of action
8 and dismissing Apothecon's state law claims for lack of standing.
9 See Geneva Pharms. Tech. Corp. v. Barr Labs., Inc., 201 F. Supp.
10 2d 236 (S.D.N.Y. 2002).

11 BACKGROUND

12 A. The Parties

13 Plaintiff Apothecon, Inc. (Apothecon) is a wholly-owned
14 subsidiary of pharmaceutical giant Bristol-Myers Squibb, and
15 plaintiff Geneva Pharmaceuticals Technology Corp. (Geneva), the
16 successor-in-interest to Invamed, Inc., is a wholly-owned
17 subsidiary of Novartis. In June 1996 Apothecon and Geneva
18 entered into a five-year Development and Supply Agreement to
19 develop, manufacture, and market generic pharmaceutical drugs,
20 including generic warfarin sodium. The parties dispute the
21 precise nature of the relationship between Apothecon and Geneva,
22 which as we explain later affects whether Apothecon has standing
23 to sue.

24 Defendant Barr Laboratories, Inc. (Barr) is a competing
25 manufacturer of generic warfarin sodium. Defendant Brantford
26 Chemicals, Inc. is a Canadian corporation that, prior to July

1 1996, was known as ACIC (Canada) Inc. (hereafter ACIC/Brantford).
2 ACIC/Brantford is a supplier of various chemicals used in
3 manufacturing pharmaceutical drugs, including clathrate. An
4 exclusive dealing contract between Barr and ACIC/Brantford is a
5 key issue in this litigation.

6 The other defendants are Dr. Bernard C. Sherman, a Canadian
7 citizen who is the beneficial owner of all the stock of defendant
8 Apotex, Inc., a Canadian company with its principal place of
9 business in Weston, Ontario. Dr. Sherman is also a substantial
10 shareholder of Barr and was a member of its board of directors.
11 In addition, Dr. Sherman, through Apotex, now controls 100
12 percent of the shares of ACIC/Brantford, so he is clearly an
13 important figure in the events we discuss.

14 B. Drug Industry

15 1. Generic Pharmaceutical Drugs

16 We believe it helpful to describe at the outset the place of
17 generics in the drug industry. Generic drugs are chemically
18 identical versions of branded drugs and cannot be put on the
19 market until the patent on the branded drug has expired. Generic
20 drugs are typically sold at a substantial discount from the name
21 brand drug. To market and distribute such a drug in the United
22 States, manufacturers must receive approval from the United
23 States Food and Drug Administration (FDA). A generic
24 manufacturer files an Abbreviated New Drug Application with the
25 FDA to establish that its drug is therapeutically equivalent to
26 the innovator drug.

1 As part of the approval process, pharmaceutical companies
2 must identify the supplier of the active pharmaceutical
3 ingredient they intend to use in manufacturing the product.
4 Ingredient suppliers, such as ACIC/Brantford, submit a Drug
5 Master File (Master File) to the FDA which summarizes the
6 equipment, manufacturing process, and control measures used to
7 prepare the particular ingredient. The supplier submits a
8 reference letter to the FDA on behalf of a particular
9 manufacturer, stating that it will follow the methods in its
10 Master File for that manufacturer.

11 The parties dispute the effect of a Master File reference
12 letter. Plaintiffs maintain it is industry practice for such a
13 reference letter effectively to bind a supplier actually to
14 provide the chemical to the manufacturer. They also state that
15 manufacturers and suppliers generally do business in reliance on
16 oral agreements. Defendants respond that the filing of a
17 reference letter is nothing more than a preliminary action that
18 creates no obligation on the part of the supplier.

19 The FDA rates a generic product as AB equivalent if it is a
20 bioequivalent to the branded product. The generic warfarin
21 sodium products currently on the market all have been rated as AB
22 equivalent to the branded drug Coumadin. Despite this rating,
23 generic drugs may have some minor differences from the branded
24 drug, such as the water content, crystalline structure, and
25 particle size of the active ingredient.

2. Warfarin Sodium

Warfarin sodium, the drug at the root of this litigation, is an oral anti-coagulant medication prescribed by a physician and taken in tablet form. This drug thins the blood and helps prevent blood clots that can cause strokes and heart attacks. Warfarin sodium is viewed as a narrow therapeutic index drug because the dosage has a narrow range of therapeutic value: the range between too low a dose, which is ineffective, and too high a dose, which may cause harmful side effects, is narrow. Its active ingredient is known as "bulk" warfarin sodium or warfarin sodium clathrate. The parties dispute whether the process to make clathrate is simple or complex; plaintiffs assert it can take years to develop a process to produce clathrate.

For nearly 50 years warfarin sodium has been manufactured by DuPont under the well-known brand name Coumadin. Although DuPont's patent for Coumadin expired in 1962, it remained the only manufacturer of warfarin sodium for the next 35 years. Its annual sales eventually exceeded \$500 million. Several companies received FDA approval to market warfarin-related products in the 1980's, but these products were unsuccessful.

In 1990 the New England Journal of Medicine published the results of two studies that created renewed interest in the efficacy of warfarin sodium. A few companies thereafter began the process of gaining approval to enter the warfarin sodium market. Currently, four companies sell warfarin sodium in the United States: DuPont, with Coumadin since 1956; Barr, with

1 generic warfarin sodium since July 1997; Geneva, with generic
2 warfarin sodium since October 1998; and Taro Pharmaceutical
3 Industries Ltd. (Taro), which has marketed generic warfarin
4 sodium since September 1999. Key for a manufacturer to the
5 production of warfarin sodium is obtaining a source of clathrate.

6 C. Obtaining a Source of Clathrate

7 1. Defendant Barr's Relationship with Defendant ACIC/Brantford

8 In the early 1990's Barr identified warfarin sodium as a
9 product with high barriers to entry because of the difficulty in
10 procuring commercial quantities of clathrate. Barr began to
11 research potential suppliers, and in 1991 it discussed purchasing
12 clathrate from ACIC/Brantford. ACIC/Brantford confirmed that it
13 would be able to produce commercial quantities of clathrate. In
14 February 1991 Barr placed a small order for it. On March 15,
15 1995 ACIC/Brantford filed a Master File for clathrate, and on
16 April 3, 1995, it provided a reference letter to the FDA in
17 support of Barr's warfarin sodium Abbreviated New Drug
18 Application. On May 10, 1995 Barr filed its application, listing
19 ACIC/Brantford as its supplier of clathrate.

20 (a) Exclusive Arrangement Between Barr and ACIC/Brantford

21 In September 1995 the defendants entered into an exclusive
22 supply agreement pursuant to which ACIC/Brantford would supply
23 Barr with clathrate. The agreement obligated Barr to purchase
24 \$1.8 million worth of clathrate. It also provided that
25 ACIC/Brantford would supply Barr exclusively with commercial
26 quantities of clathrate until another manufacturer began selling

1 generic warfarin sodium. Barr agreed to purchase 100 percent of
2 its supply from ACIC/Brantford during the exclusivity period.
3 One week after they entered into the supply agreement, the
4 defendants executed a confidentiality agreement that for five
5 years prohibited either party from disclosing "valuable,
6 proprietary, technical, commercial and other confidential
7 information."

8 This agreement only covered commercial quantities of
9 clathrate. Hence, it did not prohibit ACIC/Brantford from
10 selling small samples or developmental quantities, or from acting
11 as a broker between manufacturers and other suppliers. The
12 agreement also permitted Barr to purchase small quantities of
13 clathrate from other sources in order to qualify that supplier as
14 an alternate source.

15 (b) ACIC/Brantford Becomes Barr's Only Source

16 From September 1995 through September 1996, Barr ordered
17 larger shipments of clathrate from ACIC/Brantford, the last of
18 which was shipped in February 1997. On March 26, 1997, the FDA
19 approved Barr's application and authorized it to begin marketing,
20 which it did starting in July 1997. The FDA determined that
21 Barr's warfarin sodium tablets were "bioequivalent, and therefore
22 therapeutically equivalent" to the name brand drug Coumadin.

23 Barr continued to place orders for large quantities of
24 clathrate from ACIC/Brantford. In a September 1997 document Barr
25 referred to ACIC/Brantford as "the only source [of clathrate]
26 available to the generic industry." The district court found

1 that Barr had attempted to secure a back-up producer, but as of
2 March 1998 had not succeeded.

3 2. Plaintiff Geneva's Search for a Source of Clathrate

4 (a) Plaintiff's Dealings Before 1996 with
5 Defendant ACIC/Brantford
6

7 Geneva's attempt to obtain a source of clathrate encountered
8 nearly insurmountable obstacles. Between 1993 and 1996 it sought
9 to obtain a clathrate supply from numerous chemical companies,
10 including Hoechst Celanese, Chemoswede, Banyan Chemicals, and
11 others. A critical issue in the present dispute is whether any
12 of these potential suppliers was in fact a viable commercial
13 source of clathrate because nearly all of plaintiff's accusations
14 depend on its theory that ACIC/Brantford's monopoly on clathrate
15 created a bottleneck for others attempting entry into the generic
16 warfarin market. At the relevant time, Geneva concluded that
17 ACIC/Brantford was its only viable supplier. But, the district
18 court found several other sources were available to plaintiffs.

19 Geneva had purchased a variety of products from
20 ACIC/Brantford during the 1980's and 90's. Dr. Panjak Dave,
21 Geneva's regulatory manager, had represented Geneva in most of
22 the prior dealings with ACIC/Brantford. Sergio Getrajdman was
23 ACIC/Brantford's sales representative responsible for sales to
24 Geneva. On September 20, 1994 when Dr. Dave contacted Getrajdman
25 to discuss the availability of clathrate, Getrajdman told him
26 that ACIC/Brantford had no exclusive arrangement with respect to
27 clathrate and that it could supply clathrate to Geneva. The next

1 day, Dr. Dave telephoned ACIC/Brantford for a price quote on a
2 small purchase and was quoted approximately \$2,500 per kg.

3 From late 1994 through early 1995, ACIC/Brantford sent
4 Geneva several samples and R&D quantities of clathrate. At one
5 point, Geneva purchased 15 kg. In March 1995 ACIC/Brantford sent
6 three additional samples along with technical information that
7 Geneva had requested. In April 1995 ACIC/Brantford sent the FDA
8 a Master File reference letter on behalf of Geneva (then known as
9 Invamed). The letter provided:

10 Dear Sir,

11 Re: WARFARIN SODIUM DMF #11387

12 Authorization is hereby given to the Food and Drug
13 Administration to refer to our Master File for WARFARIN
14 SODIUM on behalf of:

15 INVAMED, INC.

16 2400 Route 130 North

17 Dayton, NJ 08810 -- U.S.A.

18 In support of any new drug application they may file on
19 pharmaceutical preparation containing the drug
20 manufactured by us.

21 ACIC (CANADA) INC. herewith commits itself to
22 manufacture all of their pharmaceutical products in
23 accordance with the current good manufacturing
24 practices and by the methods described in this specific
25 Drug Master File, and to issue a new DMF reference
26 letter after each amendment on the above Drug Master
27 File.
28

29 In July 1995 Geneva ordered 5 more kg of clathrate at \$2,500 per
30 kg and requested ACIC/Brantford's safety and handling procedures.
31 ACIC/Brantford shipped the product along with information about
32 its procedures.

1 (b) Plaintiff's Dealings with ACIC/Brantford in 1996-97

2 From this point forward, communications between
3 ACIC/Brantford and Geneva are in considerable dispute. In the
4 background of these communications is the Barr/ACIC/Brantford
5 exclusive dealing arrangement signed in late September 1995, and
6 the confidentiality agreement signed one week later. The
7 district court found that on August 23, 1995 ACIC/Brantford's
8 Getrajdman attempted to dissuade Geneva from pursuing its FDA
9 application on the pretext that others were ahead of it, and that
10 its market share would thus be proportionally smaller. In
11 January 1996 Geneva's Dave placed an order for 12 to 14 kg of
12 clathrate from ACIC/Brantford to perform tests on a particular
13 machine. Getrajdman advised Dave that he did not know when
14 availability would permit ACIC/Brantford to accept this order.

15 Before and during 1996, Geneva avers it informed Getrajdman
16 that it would be working with ACIC/Brantford's clathrate and
17 intended to use its clathrate to file its Abbreviated New Drug
18 Application. Geneva insists it also specifically advised
19 ACIC/Brantford that it would be obligated to supply Geneva with
20 commercial clathrate once Geneva's application was approved, and
21 asserts that it received repeated assurances from ACIC/Brantford.
22 Geneva says that ACIC/Brantford never mentioned its exclusive
23 contract with Barr and never said it was unwilling or unable to
24 supply Geneva with clathrate.

25 In the spring of 1997 Dr. Dave asked Getrajdman for 100-150
26 kg of clathrate. Getrajdman responded that ACIC/Brantford would

1 be able to deliver the order as soon as the FDA approved two
2 generic manufacturers' applications for generic warfarin sodium.
3 Getrajdman gave no explanation for this condition, but it is
4 essentially consistent with the terms of the Barr/ACIC/Brantford
5 supply agreement.

6 In September 1997 Geneva received FDA approval for its
7 generic warfarin sodium application. The next day it sent
8 ACIC/Brantford an order to purchase 750 kg of clathrate for \$1.8
9 million. By October 1997 Geneva still had not received an
10 acceptance of its order, and it threatened legal action. On
11 October 20, 1997 ACIC/Brantford formally rejected Geneva's order,
12 and thereafter refused to accept further Geneva orders. It was
13 then that Geneva first learned of the exclusive deal between
14 ACIC/Brantford and Barr, and that as a result, ACIC/Brantford
15 would not be able to supply it with clathrate.

16 Finding itself suddenly without a supplier, Geneva turned to
17 Banyan Chemicals (Private) Ltd. (Banyan), an Indian manufacturer.
18 Geneva and Banyan had previously worked together on several
19 products, and in 1995 had signed a Memorandum of Understanding
20 that included a provision that Banyan would begin to develop the
21 capability to manufacture clathrate. Banyan had never
22 manufactured clathrate before, and at the time Geneva expected
23 Banyan's development process to take years.

24 After ACIC/Brantford rejected Geneva's order, Geneva decided
25 that the fastest way it could enter the market was by assisting
26 Banyan to develop a process for manufacturing clathrate. Geneva

1 and Apothecon eventually entered the generic warfarin sodium
2 market using Banyan clathrate in October 1998, after a one-year
3 delay from the date of Geneva's unfilled order to ACIC/Brantford.

4 D. Plaintiffs' Claims Against Defendants

5 Plaintiffs sued ACIC/Brantford and Barr alleging that their
6 secret exclusive dealing arrangement unfairly gave Barr exclusive
7 access to the only available source of clathrate. They further
8 assert that ACIC/Brantford repeatedly assured them that it would
9 provide them with clathrate, and that because of those assurances
10 they delayed taking steps to develop an alternative supply.
11 These circumstances, plaintiffs insist, effectively delayed their
12 entry into the generic warfarin sodium market for one year, and
13 gave Barr a monopoly in this drug during that period. Plaintiffs
14 declare that consumer prices were inflated during the exclusivity
15 period and that Barr's lengthy monopoly gave it an unfair
16 advantage as an entrenched first-mover, even after competitors
17 eventually entered the market.

18 Plaintiffs further declare that the exclusive supply
19 contract, coupled with the confidentiality agreement, amounted to
20 a contract, combination or conspiracy in restraint of trade that
21 violated § 1 of the Sherman Act and was, in effect, a conspiracy
22 to monopolize in violation of § 2. They allege in addition an
23 actual monopoly by Barr in the generic warfarin sodium market
24 that violated § 2, and declare that ACIC/Brantford misused its
25 monopoly in the clathrate market that likewise violated § 2.
26 Finally, plaintiffs aver that the acquisition of ACIC/Brantford

1 by Apotex -- and via Apotex by Dr. Sherman -- violated § 7 of the
2 Clayton Act because the acquisition lessened competition or
3 tended to create a monopoly in the generic warfarin sodium
4 market.

5 E. District Court Proceedings

6 On defendants' motion for summary judgment, the district
7 court ruled against plaintiffs on most of the crucial issues and,
8 granting defendants' motion, dismissed plaintiffs' federal
9 antitrust claims. The court ruled the relevant warfarin sodium
10 market was the entire market, including Coumadin. Since Barr had
11 little market share in this overall market, the court found no
12 monopolization of warfarin sodium. It also identified other
13 available suppliers of clathrate and ruled that ACIC/Brantford
14 was not therefore monopolizing the clathrate industry.

15 Finding the supply agreement between Barr and ACIC/Brantford
16 was the product of reasonable business decisions and had pro-
17 competitive benefits, the trial court dismissed all the Sherman
18 Act causes of action. Further, finding no evidence that Apotex's
19 purchase of ACIC/Brantford caused economic harm to plaintiffs, it
20 also dismissed the Clayton Act claim. In addition, the district
21 court ruled Apothecon was not engaged in a joint venture with
22 Geneva and therefore lacked standing to sue. From these rulings
23 and the order entered thereon, plaintiffs appeal. Geneva's state
24 law tort and breach of contract causes of action against the same
25 defendants remain before the district court during the pendency
26 of this appeal.

1 DISCUSSION

2 I Partial Summary Judgment

3 Ordinarily, a district court's grant of partial summary
4 judgment is not immediately appealable because it is not a final
5 judgment. See 28 U.S.C. § 1291; Coopers & Lybrand v. Livesay,
6 437 U.S. 463, 467 (1978) (federal appellate jurisdiction
7 generally requires a conclusive decision by the district court
8 that ends the litigation on the merits). The district court
9 entered final judgment on October 7, 2002 on the claims it
10 dismissed pursuant to Fed. R. Civ. P. 54(b).² Rule 54(b) allows
11 for the entry of a partial final judgment and thereby permits
12 immediate appeal to avoid injustice. Thus, we have appellate
13 jurisdiction. See O'Bert ex rel. Estate of O'Bert v. Vargo, 331
14 F.3d 29, 40-41 (2d Cir. 2003).

15 Summary judgment is useful "to isolate and dispose of
16 factually unsupported claims," Celotex Corp. v. Catrett, 477 U.S.
17 317, 323-24 (1986), particularly in antitrust cases. See Tops
18 Mkts., Inc. v. Quality Mkts., Inc., 142 F.3d 90, 95 (2d Cir.
19 1998). This remedy is an essential tool in the area of antitrust

² Rule 54(b) provides in pertinent part:

When more than one claim for relief is presented
in an action, whether as a claim, counterclaim,
cross-claim, or third-party claim, or when
multiple parties are involved, the court may
direct the entry of a final judgment as to one or
more but fewer than all of the claims or parties
only upon an express determination that there is
no just reason for delay and upon an express
direction for the entry of judgment.

1 law because it helps avoid wasteful and lengthy litigation that
2 may have a chilling effect on pro-competitive market forces. See
3 Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574,
4 593-94 (1986).

5 We review a grant of summary judgment de novo to ensure the
6 district court applied substantive antitrust law correctly. Tops
7 Mkts., 142 F.3d at 95. A grant of such relief is proper if there
8 are no genuine issues of material fact and the moving party is
9 entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c)
10 (2000). Upon reviewing the record, we draw all inferences and
11 resolve all ambiguities in favor of the non-moving party, here
12 plaintiffs. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255
13 (1986). In an antitrust case, however, those inferences must be
14 weighed in light of competing inferences of permissible
15 competition, and the inference of conspiracy must be found the
16 more reasonable in order for plaintiffs to escape summary
17 judgment. Matsushita, 475 U.S. at 588. With these standards in
18 mind we turn to the substantive claims.

19 II Section 2 Claims

20 Section 2 of the Sherman Act makes it an offense for any
21 person to "monopolize, or attempt to monopolize, or combine or
22 conspire with any other person or persons, to monopolize any part
23 of the trade or commerce among the several States." 15 U.S.C.
24 § 2. Plaintiffs accuse defendants of monopolizing the generic
25 warfarin market by controlling and misusing ACIC/Brantford's
26 monopoly on clathrate.

1 To establish a violation of § 2, plaintiffs must prove that
2 defendants possessed monopoly power, and willfully acquired or
3 maintained that power in the relevant market. See United States
4 v. Grinnell Corp., 384 U.S. 563, 570-71 (1966). The willful
5 acquisition or maintenance of monopoly power is to be
6 distinguished from growth or development that is the result of
7 superior product, business acumen or historical accident. See
8 id. at 571.

9 A. Defining the Relevant Market for Warfarin Sodium

10 Before proceeding further we think it helpful to define the
11 relevant market for warfarin sodium. Evaluating market power
12 begins with defining the relevant market. This inquiry will also
13 prove useful for analyzing the § 1 allegations because a market
14 definition provides the context against which to measure the
15 competitive effects of an agreement. See, e.g., Copperweld v.
16 Independence Tube Corp., 467 U.S. 752, 768 (1984) (rule of reason
17 requires "an inquiry into market power and market structure
18 designed to assess the combination's actual effect").

19 The goal in defining the relevant market is to identify the
20 market participants and competitive pressures that restrain an
21 individual firm's ability to raise prices or restrict output.
22 The relevant market is defined as all products "reasonably
23 interchangeable by consumers for the same purposes," because the
24 ability of consumers to switch to a substitute restrains a firm's
25 ability to raise prices above the competitive level. United
26 States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 395

1 (1956). Reasonable interchangeability sketches the boundaries of
2 a market, but there may also be cognizable submarkets which
3 themselves constitute the appropriate market for antitrust
4 analysis. Brown Shoe Co. v. United States, 370 U.S. 294, 325
5 (1962). Defining a submarket requires a fact-intensive inquiry
6 that includes consideration of "such practical indicia as
7 industry or public recognition of the submarket as a separate
8 economic entity, the product's peculiar characteristics and uses,
9 unique production facilities, distinct customers, distinct
10 prices, sensitivity to price changes, and specialized vendors."
11 Id. The term "submarket" is somewhat of a misnomer, since the
12 "submarket" analysis simply clarifies whether two products are in
13 fact "reasonable" substitutes and are therefore part of the same
14 market. The emphasis always is on the actual dynamics of the
15 market rather than rote application of any formula.

16 The district court ruled that the entire warfarin sodium
17 market, including Coumadin, was the appropriate market. It had
18 noted the chemical equivalence between Coumadin and generics,
19 found that customers and vendors viewed the products as
20 competing, and concluded that generics took market share from
21 Coumadin. We have performed our own analysis of the Brown Shoe
22 factors and we conclude to the contrary that in this case
23 generics alone constitute the relevant market.

24 1. Generics - A Separate Market

25 It may seem paradoxical to believe that Coumadin and generic
26 warfarin -- which have been certified by the FDA as

1 therapeutically equivalent -- are nevertheless in separate
2 markets for antitrust analysis. Functional interchangeability is
3 certainly a prima facie indication that consumers of one product
4 might be willing to switch to the other in the face of a non-
5 trivial price increase. Yet, in examining the competitive
6 pressures that affect the ability of a lone generic manufacturer
7 to raise prices or reduce output, we are persuaded that
8 competition among generics creates those restraints. We note
9 that there is not just one relevant customer group, and are
10 mindful to consider the impact that patients, doctors, third-
11 party payers, wholesalers, and chain pharmacies can have on the
12 price and output of warfarin.

13 (a) Price Differential. First, the price differential
14 between Coumadin and generics is plain, as are the variant
15 pricing trends. Barr's generic was introduced at about 70
16 percent of Coumadin's price, and has since declined to 50 percent
17 while Coumadin's price has stayed steady, creating a marked gap
18 in price between the products. Coumadin's substantially higher
19 prices is evidence of a distinct customer group with brand
20 allegiance and/or high risk sensitivity that was unwilling to
21 switch from the known brand name even in the face of a discounted
22 alternative. That this group has remained loyal despite
23 Coumadin's conspicuously higher prices strongly suggests
24 inelastic demand. More significantly, this division of customers
25 indicates there is little likelihood that price-sensitive generic

1 customers would switch to the higher-priced Coumadin when faced
2 with an increase in generic prices.

3 When other generic competitors entered the market, Barr's
4 prices dropped substantially, but Coumadin's remained virtually
5 unchanged and even rose slightly. Not only did Barr's invoice
6 prices drop a small, but statistically significant amount, but
7 more importantly Barr admitted that Geneva's presence forced it
8 to offer substantial off-invoice discounts and rebates. Barr's
9 senior vice president of sales and marketing confirmed that
10 Geneva's entry had a substantial effect on Barr's pricing,
11 especially with large chain pharmacies and wholesalers.
12 Regarding wholesalers, he testified Barr offered 15-20 percent
13 rebates after Geneva entered, and with chain pharmacies, he
14 confirmed that Geneva's entry cost Barr "many millions of
15 dollars." As one example, he noted that Geneva's entry forced
16 Barr to give rebates to the CVS and Walgreens chain pharmacies
17 each in excess of a million dollars a year.

18 (b) Brown Shoe Distinguished. Defendants urge us not to
19 evaluate the market based on pricing differentials since they
20 believe the Supreme Court rejected such analysis in Brown Shoe,
21 370 U.S. at 326. In Brown Shoe, the Court did indeed reject
22 Brown's claim that its medium priced shoes did not compete with
23 its lower priced shoes. Applying Brown Shoe to the instant case,
24 the district court agreed with defendants' position and held that
25 "a division of the product lines based on 'price/quality' was

1 'unrealistic.'" 201 F. Supp. 2d at 269 (quoting Brown Shoe, 370
2 U.S. at 326). We cannot adopt this reasoning.

3 In Brown Shoe, customers and vendors viewed the differently
4 priced shoes as competing, and the Court simply clarified that a
5 price differential alone should not override observed market
6 conditions. Further, in Brown Shoe there was a continuous
7 spectrum of pricing, leading the court to conclude "[i]t would be
8 unrealistic to accept Brown's contention that, for example, men's
9 shoes selling below \$8.99 are in a different product market from
10 those selling above \$9.00." Brown Shoe, 370 U.S. at 326. Here
11 we find a substantial gap in pricing indicative of separate
12 markets. Nor do we treat pricing as dispositive, but rather use
13 pricing trends as one indicator of the impact each market
14 participant has on overall price and output.

15 (c) Inelastic Demand. We also conclude that Coumadin's
16 customers are displaying strongly inelastic demand. Overall
17 generic penetration has not been as significant in the warfarin
18 market as in other drug markets of comparable size: Barr's CEO
19 testified that generic penetration after one year can be as high
20 as 60 percent, but Barr projected only 35 percent penetration
21 after a year and in fact captured just 8 percent of the warfarin
22 market. Three-and-a-half years after generic warfarin was
23 introduced, the generic substitution rate was just over 30
24 percent despite prices that were 40 percent lower than Coumadin.
25 Such results indicate a substantial customer base that has not
26 responded to lower prices.

1 Customers that have remained with Coumadin clearly do not
2 perceive generics to be a reasonable substitute for it.
3 Conversely, price-sensitive customers have flocked to the cheaper
4 generic and are likely to view another inexpensive generic as a
5 reasonable substitute. Plaintiffs' evidence suggests that upon
6 generic entry, the consumer base split such that Coumadin and
7 generics each faced smaller, distinct consumer groups.

8 Plaintiffs have offered evidence supporting plausible
9 justifications for this trend. The narrow therapeutic index
10 status of the drug may be having some effect on the
11 risk-sensitivity of patients. Since proper dosing is tricky,
12 patients must go through a lengthy introductory period of closely
13 monitored dosage by their attending physician. Patients
14 concerned about the potential for dosage problems may be
15 especially unlikely to switch from a known entity even though
16 they have to pay a higher price. Also, since Coumadin was the
17 sole manufacturer of warfarin sodium for 35 years, there has been
18 a lengthy opportunity to develop strong brand association and
19 loyalty among patients and doctors.

20 (d) Different Distribution Chains. In addition, the
21 distribution chain for generics is different in important ways
22 from that of Coumadin. Wholesalers and chain pharmacies
23 frequently stock Coumadin plus one generic version. Thus, for a
24 substantial customer base, generic warfarin manufacturers compete
25 among themselves for one slot rather than with Coumadin.
26 Plaintiffs also offered evidence that Coumadin has been marketed

1 primarily to physicians, while generics target wholesalers and
2 chain pharmacies. Not surprisingly, Geneva's entry affected
3 Barr's pricing primarily with respect to wholesalers and chain
4 pharmacies.

5 (e) Industry Recognition. Industry recognition is also
6 notable. Although the industry undoubtedly acknowledges that
7 Coumadin competes to some extent with generics, generic
8 manufacturers treat each other as the entities which most
9 directly affect their pricing and output decisions. With respect
10 to generic drugs generally, Dr. Sherman, defendant
11 ACIC/Brantford's principal owner, stated:

12 Given that generic drug products are
13 universally cheaper than original brand
14 products, the first generic drug company,
15 upon entry of a particular drug market, will
16 automatically capture a sizeable portion of
17 the sales of the drug, thereby creating the
18 generic drug market.

19 When subsequent generic drug companies
20 enter the market in respect of the particular
21 drug, these generic companies compete with
22 the first and prior generic drug companies as
23 to the share of the generic drug market.
24 . . . As a result, from the standpoint of the
25 patentee drug company it matters not whether
26 there is one, two, ten or twenty generic drug
27 companies since each successive generic
28 entrant only gains market share from the
29 previous generic competitors and not from the
30 patentee.

31
32 Several Apothecon employees also testified that they make
33 pricing decisions as to generic warfarin sodium based on generic
34 competition, not competition from Coumadin. Apothecon's former
35 product manager stated "We compete against other generics, we do
36 not compete against Coumadin. . . . [W]e do not set our prices

1 based on what the brand is doing." Plaintiff's expert pointed
2 out that Barr's website stated, "Barr focuses its generic
3 research and development activities on generic products that have
4 significant barriers to entry," and such barriers would apply
5 only to generic competitors.³

6 Barr's own price predictions for generic warfarin sodium led
7 it to conclude that it could charge 70 percent of Coumadin's
8 price in the first year, 50 percent in the second year and 40
9 percent in the third year. These predictions assumed one generic
10 competitor entering in the second year and another entering in
11 the third year. This effect is consistent with the literature on
12 generic drug competition describing how generic pricing is a
13 function of the number of generic competitors. See generally
14 Congressional Budget Office, How Increased Competition from
15 Generic Drugs Has Affected Prices and Returns in the
16 Pharmaceutical Industry, at 32 (1998); Roy Levy, The
17 Pharmaceutical Industry: A Discussion of Competitive and
18 Antitrust Issues in an Environment of Change (Federal Trade
19 Commission Bureau of Economics Staff Report, Mar. 1999); David
20 Reiffen & Michael R. Ward, Generic Drug Industry Dynamics

³ We note that Barr appears to have changed the wording on its website, although consistent with that language the site now also states that "[Barr's] generic product development activities focus on the selection of pharmaceutical products where these selection criteria may limit the potential number of generic competitors." See <http://www.barrlabs.com/pages/corphist.html> (last visited June 7, 2004) (emphasis added). Since the district court did not have the benefit of this statement before it, we do not rely on it in reaching our decision.

1 (Federal Trade Commission, Working Paper No. 248, Feb. 2002), at
2 <http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf>
3 (last visited June 4, 2004).

4 (f) No Supply Substitution. Moreover, the evidence shows
5 there was very limited potential for supply substitution in the
6 generic market. A manufacturer's ability to raise prices or
7 reduce output is not only constrained by current substitutes but
8 also by actual or potential competitors capable of providing new
9 competition quickly with little sunk costs.

10 We can readily dismiss potential substitution from all
11 entities other than DuPont. We find evidence of particularly
12 high barriers to entry resulting both from limited supply of
13 clathrate and from the regulatory requirements to sell generics.
14 We find no evidence that other generic pharmaceutical
15 manufacturers could quickly and easily have entered the warfarin
16 market if generic warfarin prices were raised substantially above
17 marginal cost. Barr's own process of reaching the warfarin
18 market, which began in 1991 and ended in 1997, belies its claim
19 of easy entry, as does its mission statement which acknowledges
20 seeking drugs with high barriers to entry.

21 2. DuPont Unlikely to Enter Generic Market

22 Competition from DuPont is not so straightforward. DuPont
23 already sold warfarin sodium, had access to a clathrate supply,
24 and had contacts in the distribution chain. However, DuPont
25 would have had strong incentives not to introduce its own
26 generic, even if it felt that Barr was charging supra-competitive

1 prices. No doubt it observed that within a few years, there
2 would be increased competition among generics, and its own entry
3 would simply accelerate the decline of generic prices and thereby
4 accelerate the segmentation of the market. Since at best it
5 would be substituting sales of a generic at a lower price for
6 sales of Coumadin at a higher price, all with the same cost of
7 production, DuPont's entry into the generic market could only
8 hurt its bottom line. DuPont likely could only have had success
9 selling generic warfarin if it had been able to seize the
10 substantial advantage that a first mover has in the generic
11 market, and even then, it obviously found any advantage would be
12 outweighed by the erosion of sales of Coumadin. DuPont had
13 substantial success maintaining its customer allegiance at the
14 higher price, and we believe it posed no threat of generic entry
15 and therefore no check on generic prices.

16 In sum, the totality of the evidence convinces us that once
17 Barr entered the market, the market became segmented so that
18 Coumadin and Barr each had smaller, distinct customer groups.
19 After the initial segmentation, Barr's price was impacted much
20 more by Geneva's entry than by Coumadin. For example, plaintiffs
21 have pointed to data indicating that Geneva's entry affected
22 Barr's pricing of its dosage strengths also sold by Geneva, but
23 not of its other dosage strengths. This evidence strongly
24 suggests to us that competition among generics is the competitive
25 force that restrains a single generic competitor from raising
26 prices or restricting output.

1 We therefore hold that the relevant market for our purposes
2 is the market for generic warfarin sodium tablets.

3 B. Monopoly Power

4 We turn now to discuss proof of monopoly power in the
5 generic warfarin sodium market. Monopoly power is "the power to
6 control prices or exclude competition." E.I. du Pont, 351 U.S.
7 at 391. It can be proven directly through evidence of control
8 over prices or the exclusion of competition, or it may be
9 inferred from a firm's large percentage share of the relevant
10 market. Tops Mkts., 142 F.3d at 98. Plaintiffs seek to
11 demonstrate monopoly power through both methods.

12 1. Direct Evidence of Monopoly Power

13 With respect to direct evidence, plaintiffs primarily rely
14 on the report of their expert, Dr. Robert Lerner. The expert's
15 market analysis led him to conclude that in the absence of
16 generic competition Barr had charged a monopoly price that lasted
17 until plaintiffs finally entered the market. Plaintiffs offered
18 evidence to show that after their entry Barr lowered its price
19 and offered substantial price discounts and rebates. Plaintiffs
20 contend this is direct proof that Barr controlled prices during
21 its period of exclusivity. Further, they assert that Barr's
22 first-mover advantage led to substantial entrenchment, such that
23 it continued to control 80 percent of generic sales several years
24 after it faced competition. This, they think, constituted
25 exclusion of competition, which likewise is direct proof of
26 monopoly power.

1 This direct proof is at best ambiguous. We recognize
2 plaintiffs' pricing proof may of course be indicative of monopoly
3 power. However, absent from plaintiffs' proffer is any analysis
4 of Barr's costs. Hence, we do not know whether the allegedly
5 elevated prices led to an abnormally high price-cost margin. See
6 2A Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 501
7 (1995). Nor do plaintiffs present direct evidence that
8 defendants restricted output, asking us to infer the basis for
9 the higher prices. Moreover, plaintiffs' assertion with regard
10 to Barr's continuing high percentage market share is not direct
11 evidence, but rather requires that we engage in the sort of
12 inference more appropriate for market share analysis.

13 Where direct evidence is unavailable or inconclusive, as
14 here, monopoly power may be inferred from high market share.
15 Although market share is not functionally equivalent to monopoly
16 power, it is nevertheless highly relevant to the determination of
17 monopoly power. Tops Mkts., 142 F.3d at 98.

18 2. Monopoly Power Through Market Share

19 Having defined the relevant market, we consider whether
20 Barr's high market share leads to a fair inference of monopoly
21 power. Courts will only draw that inference after considering
22 market share in conjunction with other characteristics of the
23 market, such as "the strength of competition, the probable
24 development of the industry, the barriers to entry, the nature of
25 the anticompetitive conduct and the elasticity of consumer

1 demand." Int'l Distribution Ctrs., Inc. v. Walsh Trucking Co.,
2 812 F.2d 786, 792 (2d Cir. 1987).

3 Defendants do not dispute that Barr was the sole
4 manufacturer of generic warfarin sodium during the period from
5 July 1997 through October 1998. This alone creates a strong
6 inference of monopoly power. The nature of defendant's pricing
7 activities also supports an inference of monopoly power.
8 However, we think there is a question of fact as to whether this
9 is the type of competitive advantage about which the antitrust
10 laws should be concerned. Every first mover into a new market
11 has a monopoly during its initial period of exclusivity. The
12 antitrust laws have not been applied to condemn the transient
13 advantage inherent in being a first mover because to do so would
14 stifle innovation. See AD/SAT, a Division of Skylight, Inc. v.
15 Associated Press, 181 F.3d 216, 229 (2d Cir. 1999) (per curiam)
16 (quoting 2A Areeda & Hovenkamp, supra, ¶ 506d, at 103
17 ("[T]ransitory power may safely be ignored by antitrust law"
18 because market forces would end that power fairly quickly));
19 Dimmitt Agri Indus., Inc. v. CPC Int'l Inc., 679 F.2d 516, 530
20 (5th Cir. 1982) ("Transitory control over prices, ever present in
21 a competitive economy . . . is not the subject of the completed
22 monopolization offense.")).

23 Barr's period of exclusivity lasted about 15 months,
24 although plaintiffs allege that the effects of this exclusivity
25 period lasted much longer. This may or may not be of sufficient
26 duration to have significant anti-competitive effects. In any

1 event, whether Barr's advantage should be viewed as a transitory
2 advantage inherent in being a first entrant or a substantial
3 impediment to competition involves a genuine question of material
4 fact. Plaintiffs have satisfied their burden of producing
5 evidence that the effects of Barr's advantage were substantial
6 and that competition overall was impaired. Such an issue of
7 material fact should not be resolved at the summary judgment
8 stage because to do so requires weighing the evidence, which is a
9 matter left for a jury.

10 The final element of the monopolization charge is that
11 defendants must have willfully acquired or maintained their
12 advantage as opposed to succeeding through a superior product,
13 business acumen or historical accident. On this point,
14 plaintiffs have alleged a conspiracy between Barr and
15 ACIC/Brantford, embodied in their exclusivity agreement and in
16 their actions towards plaintiffs. Plaintiffs believe Barr and
17 ACIC/Brantford sought to leverage ACIC/Brantford's monopoly in
18 the clathrate market in a manner that attempted both to assure
19 Barr's monopoly in the downstream generic warfarin sodium market
20 and simultaneously helped reinforce ACIC/Brantford's monopoly in
21 the clathrate market. Because of the close connection of these
22 allegations to the dynamics of the clathrate market, we discuss
23 the evidence of intent as part of our analysis of the clathrate
24 market, where we conclude that plaintiffs presented satisfactory
25 evidence that Barr willfully acquired or maintained its monopoly,

1 see Grinnell Corp., 384 U.S. at 570-71, and that both defendants
2 conspired to do so.

3 III Clathrate Market

4 A. Section 2 Claims Stated

5 Plaintiffs also allege that ACIC/Brantford monopolized the
6 clathrate supply market and that both defendants, ACIC/Brantford
7 and Barr, conspired to do so. Defendants respond that
8 plaintiffs' arguments regarding ACIC/Brantford's asserted
9 clathrate monopoly relate to the purported effort to monopolize
10 the generic warfarin sodium market. They maintain that
11 plaintiffs have not contended that ACIC/Brantford's actions had
12 the effect of keeping other clathrate suppliers out of the
13 clathrate market and that therefore plaintiffs' § 2 claim in the
14 clathrate market must fail.

15 Defendants are correct that § 2 is often concerned with the
16 exclusion of competitors. However, plaintiffs contend that
17 ACIC/Brantford and Barr conspired to mislead and deceive them in
18 order to delay Geneva from pursuing and developing an alternate
19 supply of clathrate. They have thus successfully alleged that,
20 by so preventing the plaintiffs from developing a rival to
21 ACIC/Brantford, the defendants "willful[ly] . . . maint[ained]"
22 ACIC/Brantford's monopoly. Id. Although the plaintiffs were not
23 themselves excluded from the clathrate market, they have
24 sufficiently stated § 2 claims regarding that market and have
25 standing to bring them, see Blue Shield of Va. v. McCreedy, 457
26 U.S. 465, 479-81 (1982). Thus, it is a question for the jury

1 whether ACIC/Brantford had monopoly power in the clathrate
2 market, and if so, whether defendants abused ACIC/Brantford's
3 market power.

4 B. No Other Viable Suppliers of Clathrate Available

5 In determining if ACIC/Brantford had monopoly power in the
6 clathrate supply market, it is crucial to determine whether other
7 suppliers besides ACIC/Brantford were available as potential
8 generic warfarin sodium manufacturers.

9 The district court found other suppliers of clathrate were
10 available to plaintiffs in 1995-98, and ruled that ACIC/Brantford
11 did not have a sizeable market share. Specifically, it
12 identified Hoechst Celanese and Chemoswede as companies prepared
13 to sell clathrate. It also mentioned several other manufacturers
14 that could have developed the capability of processing clathrate,
15 if plaintiffs had pursued the matter. However, viewing the facts
16 as we must in the light most favorable to plaintiffs, the issue
17 of whether ACIC/Brantford effectively was the only source
18 available to generic manufacturers in 1995-98 is in sufficient
19 dispute so that it should not have been resolved on a motion for
20 summary judgment. We enumerate ten other possible suppliers of
21 clathrate. They are: Hoechst, Chemoswede, Lachema, Taro,
22 Arenol, Vinchem, Diosynth, Banyan, Chemagis, and Shanghai.
23 Plaintiffs' proof suggests that for one reason or another none of
24 them could actually be considered a viable supplier of clathrate
25 during the relevant time period.

1 Hoechst. Geneva received R&D samples from Hoechst and
2 considered entering into a supply agreement with Hoechst.
3 Plaintiffs raise serious questions about Hoechst's willingness
4 and ability to provide clathrate. Hoechst had not filed a Drug
5 Master File with the FDA and indicated it would not be able to
6 for some time. According to plaintiffs, Hoechst was experiencing
7 difficulties with the stability of its clathrate production,
8 reporting environmental problems due to clathrate's toxicity that
9 were hampering its development. Hoechst had little interest in
10 solving this problem. A Hoechst interoffice memo describes
11 Geneva's frustration with Hoechst's clathrate development
12 problems, and describes Dr. Patel's suggestion that if they could
13 not provide better service they should not be in the business.
14 The memo's author states "I resisted the urge to tell him that we
15 are likely to accept his advice." Hoechst eventually sold the
16 only facility it had working to develop clathrate. Barr's
17 purchasing manager Mary Casatelli confirmed that Barr considered
18 Hoechst's viability as a clathrate supplier to be a "moot point"
19 because it had decided to close its manufacturing facility and
20 put it up for sale.

21 Chemoswede. Chemoswede was DuPont's supplier of clathrate
22 for Coumadin. As of mid-1995 Chemoswede was under contract to
23 supply clathrate exclusively to DuPont, and DuPont purchased
24 Chemoswede outright in 1997. Barr's Paul Bisaro testified in his
25 deposition that Chemoswede would not sell clathrate to Barr
26 because of its obligations to DuPont. Barr's chairman Bruce

1 Downey also testified that the result of DuPont's purchase of
2 Chemoswede was that Chemoswede would no longer supply to the
3 generic industry. Despite this testimony, the district court
4 decided that Chemoswede should be considered an available source.
5 Although acknowledging that "most or all of its clathrate was
6 dedicated to DuPont," the court believed that "internal or
7 captive sources of a product are still included in the relevant
8 market." 201 F. Supp. 2d at 272. In light of our market
9 definition of generic warfarin sodium, this conclusion no longer
10 is apt. The question here is availability of clathrate to
11 generic manufacturers, which affects the supply of generic
12 warfarin sodium. Chemoswede's clathrate affects neither, and
13 therefore has no impact on a putative monopolist's ability to
14 control supply of generic warfarin.

15 Lachema. Plaintiffs ordered a 15 kg sample of clathrate
16 from Lachema in February 1998. When Lachema failed to fill this
17 order after a 6-9 month delay, Geneva abandoned the order
18 realizing that Lachema could not supply them. Barr's Mary
19 Casatelli testified that when she left Barr in November 1997, she
20 had concluded "there was no way" Lachema could have been an
21 approved supplier.

22 Taro. Sergio Gertrajdman, an employee of ACIC/Brantford,
23 testified that before he left he attempted to secure clathrate
24 from Taro, but Taro refused to sell. Plaintiffs presented
25 evidence that Taro did not have a Master File on file with the

1 FDA and did not enter the market until September 1999, two full
2 years after Geneva sought a clathrate source.

3 Arenol. Arenol evidently worked on a clathrate process in
4 1997 and 1998, although it too did not file a Master File for
5 clathrate. Arenol's plant was eventually destroyed by fire in
6 August 1998, but even at that late date, plaintiffs maintain that
7 Arenol had not even begun to prepare to supply clathrate.

8 Vinchem. Vinchem was a broker, not a manufacturer of
9 clathrate. Plaintiffs at one point received some clathrate from
10 Vinchem, but they were unable to determine that the source had
11 filed the requisite Master File. Geneva ultimately concluded
12 that Vinchem was unable to deliver any clathrate.

13 Diosynth. Diosynth potentially could have provided
14 clathrate, but had no viable process for synthesizing or
15 manufacturing clathrate in 1996-97. According to plaintiffs,
16 Diosynth was unable to develop a process until September 1999,
17 two years after Geneva's Abbreviated New Drug Application was
18 approved.

19 Banyan. In 1995, Geneva and Banyan amended their existing
20 development agreement to include development of clathrate. At
21 the time, Banyan had no facilities capable of producing clathrate
22 nor did it have a process for manufacturing clathrate. Because
23 Banyan was not expected to have clathrate production capabilities
24 for a substantial period of time, plaintiffs did not consider
25 Banyan a viable source. After ACIC/Brantford rejected
26 plaintiffs' purchase order in 1997, plaintiffs made an effort to

1 accelerate Banyan's capabilities, and were able to enter the
2 market using Banyan clathrate in October 1998.

3 Chemagis. Geneva met with Chemagis to discuss the purchase
4 of clathrate. Chemagis never filed a Master File for clathrate.
5 Chemagis refused to develop a process to manufacture clathrate
6 unless plaintiffs paid the upfront costs of establishing a new
7 facility. According to plaintiffs, Chemagis' development time
8 frame was too long, the startup costs were prohibitive, and its
9 production capability was at best speculative.

10 Shanghai. Geneva received samples of clathrate from
11 Shanghai in early 1997. However, Shanghai had not filed a Master
12 File for clathrate, and Geneva understood that its facilities to
13 produce clathrate had not been built. Believing Shanghai was in
14 the very early stages of development, plaintiffs concluded it was
15 even further behind than Banyan.

16 It is significant that plaintiffs' description of the state
17 of the clathrate industry in 1995-98 is consistent with Barr's
18 own records and reports. A Barr memorandum to investors
19 commented that warfarin sodium featured "unique raw material
20 sourcing issues," and that it had secured "an exclusive source of
21 active ingredient that to date is the only source available to
22 the generic industry." Barr's CEO Bruce Downey also testified
23 that Barr had been actively looking for a backup material
24 supplier in the period before its launch, and he stated "it was
25 our judgment that there were no others, other than the one that
26 we had worked with."

1 The factual dispute over the availability of clathrate
2 precludes any definitive assessment of ACIC/Brantford's power in
3 the clathrate industry, making the grant of summary judgment on
4 this issue inappropriate.

5 C. Willful Acquisition or Maintenance of Monopoly Power

6 We have found material questions of fact regarding Barr's
7 monopoly power in the generic warfarin sodium market and
8 ACIC/Brantford's monopoly power in the clathrate industry.
9 Plaintiffs have presented sufficient evidence on both of these
10 issues to satisfy their burden at the summary judgment stage. To
11 succeed on their claims however plaintiffs must also demonstrate
12 that defendants willfully acquired or maintained their monopoly
13 power as opposed to having achieved their advantage through
14 superior business practice or historical accident.

15 Several Barr statements can be interpreted as suggesting an
16 intent to seize the sole supply of clathrate in order to
17 monopolize the generic warfarin market. A memorandum dated April
18 14, 1997 from Mary Casatelli, Barr's purchasing manager, to Paul
19 Bisaro, Barr's vice president and general counsel, identifies
20 just two manufacturers capable of making clathrate, DuPont
21 Chemoswede and ACIC/Brantford. The memo closes with the
22 statement, "We should give thought to the strategy we should
23 pursue in order to deny a viable source to Invamed." Mary Petit,
24 Barr's director of pharmacology and senior vice president of
25 operations, added a handwritten note to the memorandum: "Paul -
26 What is this worth to us - Will purchasing the Coventry

1 facility's supply (even tho we can't use it) be less \$\$ than our
2 losses if Invamed enters the market? Would ACIC/Brantford or
3 Barr purchase the Coventry R/M and sell to ACIC/Brantford's
4 overseas customers to keep them out of supplying Invamed?"
5 Defendants attempt to portray these notes as isolated thoughts of
6 non-decision-making employees, but we think a jury should decide
7 what weight should be given these statements.

8 Later in 1997 a "Product Development Strategy" prepared for
9 a Barr board of directors' meeting in September 10-11, 1997,
10 states that Barr focuses on lower sales volume drugs with high
11 barriers to entry that limit competition. The memorandum
12 describes Barr's efforts to secure a source of raw materials for
13 generic warfarin sodium and notes that its "investment of time
14 and capital resulted in an exclusive source of active ingredient
15 that to date is the only source available to the generic
16 industry."

17 Further, an internal Barr memorandum titled "Branded
18 Pharmaceutical Company Generic Defense Strategies" contains a
19 section entitled "Preserving Market Share: Warfarin Case Study"
20 that includes the headline "Block Generic Competition by
21 Controlling Raw Materials." Ms. Casatelli believed that denying
22 Geneva a source of clathrate was "simply good business practice."
23 Barr's chairman, Bruce Downey, confirmed that Barr was not
24 successful in finding backup clathrate suppliers, and he believed
25 generic competition would be limited due in part to the small
26 number of FDA-approved raw material suppliers.

1 Plaintiffs also provided evidence relating to why they
2 believed they had an oral contract with ACIC/Brantford. Sergio
3 Getrajdman, ACIC/Brantford's sales representative who dealt with
4 Geneva, recalled telling Geneva's Dr. Dave that ACIC/Brantford
5 could provide clathrate to Geneva. Getrajdman stated that he had
6 not been aware that ACIC/Brantford had even considered an
7 exclusive agreement on clathrate: "I never - I would have never
8 approached [Dr. Dave] with the product had there been discussion
9 of an exclusive." Getrajdman testified that he thought
10 ACIC/Brantford was obligated to provide clathrate to Geneva and
11 that he repeatedly advised people at ACIC/Brantford of that
12 obligation. Antoniette Walkom, who was the author of
13 ACIC/Brantford's Master File reference letter in support of
14 Geneva, testified similarly that the letter reflected a
15 commitment by ACIC/Brantford to provide clathrate to Geneva.

16 In September 1996 after ACIC/Brantford acquired ACIC,
17 ACIC/Brantford wrote to Dr. Dave and stated, "According to our
18 records, letters of access to the following U.S. files have been
19 provided to your firm. Please kindly review the list below and
20 notify us of any omissions . . ." Warfarin sodium was on the
21 list. Geneva's Dr. Mahendra Patel testified that on several
22 occasions, ACIC/Brantford actively encouraged Geneva to develop
23 warfarin sodium using ACIC/Brantford clathrate, and repeatedly
24 solicited Geneva's business.

25 After the exclusive agreement was signed, ACIC/Brantford was
26 elusive in its responses to Geneva's requests for more clathrate.

1 Getrajdman wrote in a memo dated August 23, 1995, "I contacted
2 [Geneva's Mahendesh] Patel with the strategy we discussed Friday
3 in Toronto, namely, to discourage him from proceeding w/
4 development on the pretext that others were ahead of him and his
5 market share would thus be proportionately smaller. I was
6 unsuccessful . . ." ACIC/Brantford's Telemagic printout contains
7 entries of Getrajdman's response to Dr. Dave's January 12, 1996
8 request for clathrate: he stalled until February 5, "but we must
9 decide whatever I am to tell Invamed by then: we had the chance
10 to tell them face to face in Germany, but [ACIC/Brantford
11 President Luciano Calenti] felt the time was not right."

12 ACIC/Brantford evidently developed several strategies for
13 how to tell Geneva that they would no longer provide clathrate.
14 One strategy was to give the false story that for capacity
15 reasons, they would be moving their production facility to
16 Mexico. Getrajdman noted at the bottom of a memo, "Time to bite
17 the bullet. If I go with the switching site story, I need dates
18 as soon as possible." He also placed an entry in the Telemagic
19 machine dated January 16, 1996: "The fact that they're putting
20 things in writing makes me nervous." As late as mid-1997, two
21 full years after the exclusive supply agreement was signed, it is
22 clear that ACIC/Brantford still had not told Geneva it could not
23 supply clathrate.

24 Additionally, plaintiffs provided some evidence that Barr
25 was involved with ACIC/Brantford in the decision to reject
26 Geneva's purchase order in September 1997. Barr Chairman Bruce

1 Downey stated that Barr was contacted by ACIC/Brantford and
2 informed that ACIC/Brantford had received a purchase order from
3 Geneva for commercial quantities of clathrate, "which sale was
4 prohibited by our contract. And we were asked whether we were
5 going to stand on our rights as embodied in that contract and we
6 said yes." Defendants dispute their involvement in the decision,
7 but given the totality of the circumstances suggesting intent to
8 monopolize, we are inclined to allow a jury to make that factual
9 determination.

10 The evidence as a whole could lead a reasonable jury to
11 conclude that Barr and ACIC/Brantford intended to take advantage
12 of ACIC/Brantford's clathrate monopoly, intended to create a
13 monopoly for Barr in the generic warfarin sodium industry, and
14 intended to keep their agreement secret so that Geneva would not
15 take steps to develop an alternate source. We discuss the
16 specific evidence of agreement in the following section. While
17 there may be some pro-competitive benefits of exclusive supply
18 agreements, it is difficult to conceive of the pro-competitive
19 benefits that would be derived from this level of deception, and,
20 also, it is difficult to believe that defendants' advantage came
21 about through better business practices or historical accident.
22 The district court's grant of summary judgment on plaintiffs' § 2
23 claims must therefore be reversed.

24 IV Section 1

25 Section 1 of the Sherman Act prohibits "[e]very contract,
26 combination in the form of trust or otherwise, or conspiracy, in

1 restraint of trade or commerce among the several States." 15
2 U.S.C. § 1. As the language states, § 1 targets concerted action
3 between two or more entities. Independent conduct falls outside
4 the purview of this provision. Monsanto Co. v. Spray-Rite Serv.
5 Corp., 465 U.S. 752, 761 (1984). To prove a § 1 violation, a
6 plaintiff must demonstrate: (1) a combination or some form of
7 concerted action between at least two legally distinct economic
8 entities that (2) unreasonably restrains trade. See Tops Mkts.,
9 142 F.3d at 95; Capital Imaging Assocs., P.C. v. Mohawk Valley
10 Med. Assocs., Inc., 996 F.2d 537, 542 (2d Cir. 1993). The
11 parties agree that the conduct at issue here does not fall within
12 the narrow range of behavior that is considered so plainly anti-
13 competitive and so lacking in redeeming pro-competitive value
14 that it is "presumed illegal without further examination," that
15 is, it is illegal per se. Broad. Music, Inc. v. CBS, 441 U.S. 1,
16 8 (1979). Accordingly, the case before us is evaluated under the
17 rule of reason, and defendants' conduct will be deemed illegal
18 only if it unreasonably restrained competition. Atl. Richfield
19 Co. v. USA Petroleum Co., 495 U.S. 328, 342 (1990).

20 Under the rule of reason, the plaintiffs bear an initial
21 burden to demonstrate the defendants' challenged behavior "had an
22 actual adverse effect on competition as a whole in the relevant
23 market." Capital Imaging, 996 F.2d at 543. Because the
24 antitrust laws protect competition as a whole, evidence that
25 plaintiffs have been harmed as individual competitors will not
26 suffice. Atl. Richfield, 495 U.S. at 343-44. If the plaintiffs

1 satisfy their initial burden, the burden shifts to the defendants
2 to offer evidence of the pro-competitive effects of their
3 agreement. Capital Imaging, 996 F.2d at 543; Bhan v. NME Hosps.,
4 Inc., 929 F.2d 1404, 1413 (9th Cir. 1991). Assuming defendants
5 can provide such proof, the burden shifts back to the plaintiffs
6 to prove that any legitimate competitive benefits offered by
7 defendants could have been achieved through less restrictive
8 means. Capital Imaging, 996 F.2d at 543. Ultimately, the
9 factfinder must engage in a careful weighing of the competitive
10 effects of the agreement -- both pro and con -- to determine if
11 the effects of the challenged restraint tend to promote or
12 destroy competition. Id.

13 A. Contract, Combination or Conspiracy

14 To satisfy the concerted action requirement, plaintiffs
15 allege a conspiracy between Barr and ACIC/Brantford to restrain
16 trade in the clathrate and generic warfarin sodium markets. In
17 addition, they insist the exclusive supply and confidentiality
18 agreements themselves violate § 1. Although the district court
19 only addressed the conspiracy argument, we think the complaint
20 fairly read encompasses both allegations.

21 To withstand a summary judgment motion, plaintiffs must
22 present evidence of an actual illegal combination, and such
23 evidence must satisfactorily cast doubt on inferences of
24 independent action or proper conduct by defendants. Matsushita,
25 475 U.S. at 588. The evidence must prove defendants had an
26 intent to adhere to an agreement that was designed to achieve an

1 unlawful objective; specific intent to restrain trade is not
2 required. Capital Imaging, 996 F.2d at 545.

3 The district court ruled that there was a material question
4 of fact regarding Barr's knowledge of the interactions between
5 Geneva and ACIC/Brantford. The court held that plaintiffs'
6 evidence was sufficient to support an inference that Barr was
7 aware that ACIC/Brantford had supplied Geneva with enough
8 clathrate to file its Abbreviated New Drug Application, and that
9 it was industry practice that such supply created an implied
10 contract.

11 However, the district court then ruled the conspiracy theory
12 must fail because there was no evidence that the exclusive
13 agreement was anything but a legitimate business tactic by
14 ACIC/Brantford. It held that lack of intent by one party, here
15 ACIC/Brantford, precludes a conspiracy to monopolize. While we
16 agree with the district court's statement of the law, we believe
17 it inappropriately resolved factual disputes in reaching its
18 conclusion that there was no conspiracy.

19 The testimony as a whole as well as the various memos and
20 internal documents support an inference of conscious, concerted
21 action intended to take advantage of ACIC/Brantford's monopoly on
22 clathrate. Plaintiffs presented circumstantial evidence that
23 Barr and ACIC/Brantford conspired to control the only source of
24 clathrate available and to deceive plaintiffs so that plaintiffs
25 would not take steps to develop an alternate supply. There was
26 evidence that Barr demanded the confidentiality agreement in

1 order to delay Geneva's entry and thwart the development of
2 alternative supplies. Testimony further showed that both Barr
3 and ACIC/Brantford understood the confidentiality agreement to
4 require silence by ACIC/Brantford in its dealings with Geneva,
5 suggesting that ACIC/Brantford's deceptions were in furtherance
6 of the agreement.

7 Also, the Casatelli/Petit memorandum urging Barr to purchase
8 excess clathrate in order to block Geneva's entrance is
9 particularly damning. The district court dismissed this
10 memorandum because the court found "no evidence that this
11 document represents any employee's view but that of Casatelli and
12 Petit, nor that their views were ever acted upon." 201 F. Supp.
13 2d at 277. We doubt the soundness of this conclusion since at
14 least one was a senior executive. But, in any event, it
15 represents an improper weighing of the evidence by the court,
16 which should have instead looked at the evidence in the light
17 most favorable to the non-moving party. See, e.g., Adjustrite
18 Sys., Inc. v. GAB Bus. Servs., Inc., 145 F.3d 543, 547 (2d Cir.
19 1998).

20 We also believe the exclusive dealing arrangement itself
21 satisfies the § 1 requirement of coordinated action. Since Barr
22 was aware that clathrate was in short supply -- and in fact
23 believed ACIC/Brantford was the only available supplier -- the
24 decision to use an exclusive supply contract as opposed for
25 example to a requirements contract, as well as its demand for a
26 confidentiality clause, suggest intent to control the supply of

1 clathrate. The evidence as a whole from telephone records,
2 deposition testimony, and internal documents, indicates "a
3 conscious commitment to a common scheme designed to achieve an
4 unlawful objective." Monsanto, 465 U.S. at 768.⁴ Thus,
5 plaintiffs satisfied the concerted action requirement at this
6 stage of the litigation.

7 B. Unreasonable Restraint of Trade

8 Exclusive dealing arrangements implicate § 1 because they
9 have the potential unreasonably to exclude competitors or new
10 entrants from a needed supply, or to allow one supplier to
11 deprive other suppliers of a market for their goods. See
12 Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 45 (1984)
13 (O'Connor, J., concurring). Such agreements may also, however,
14 have pro-competitive purposes and effects, such as assuring
15 steady supply, affording protection against price fluctuations,
16 reducing selling expenses, and promoting stable, long-term
17 business relationships. See Tampa Elec. Co. v. Nashville Coal

⁴ Theorists note it usually does not further harm competition for a monopolist in one market to leverage its advantage into a monopoly in a downstream market. This is so because the firm already has a monopoly and can extract monopoly returns. See, e.g., Robert H. Bork, *The Antitrust Paradox*, 228-29, 372-75 (1978). Still, the window of monopoly opportunity is unique in this case. ACIC/Brantford recognized its period of exclusivity would be brief, and that the best way to take advantage of its exclusivity was to work with Barr to gain a monopoly in the generic warfarin sodium market. If Barr too could gain an entrenched advantage, ACIC/Brantford's clathrate advantage could last even after other clathrate suppliers entered that market. Therefore, despite allegedly possessing monopoly power, ACIC/Brantford would still have had an incentive to use that power to gain advantage downstream.

1 Co., 365 U.S. 320, 333-35 (1961). In order not to condemn the
2 positive aspects of exclusive dealing agreements, courts must
3 take care to consider the competitive characteristics of the
4 relevant market. Exclusive dealing is an unreasonable restraint
5 of trade and a § 1 violation only when the agreement freezes out
6 a significant fraction of buyers or sellers from the market.
7 Jefferson Parish, 466 U.S. at 45; cf. Standard Oil Co. v. United
8 States, 337 U.S. 293 (1949).

9 The exclusive dealing agreement in the present case is of
10 particular concern because of the alleged bottleneck in the
11 clathrate supply chain. Plaintiffs have created a material
12 dispute of fact as to whether ACIC/Brantford effectively
13 controlled the entire supply of clathrate available to generic
14 warfarin sodium manufacturers during the period at issue. There
15 is also evidence of high barriers to entry, meaning that
16 potential suppliers could not easily enter the market. To the
17 extent plaintiffs' theory is accurate, the exclusive dealing
18 agreement had the potential to freeze competitors out of the
19 generic warfarin sodium market.

20 Plaintiffs bear the initial burden to demonstrate an actual
21 adverse effect on competition. We have not required proof of
22 market power in § 1 cases. If plaintiff can demonstrate an
23 actual adverse effect on competition, such as reduced output, see
24 FTC v. Indiana Fed'n of Dentists, 476 U.S. 447, 460-61 (1986),
25 there is no need to show market power in addition. See K.M.B.

1 Warehouse Distribs., Inc. v. Walker Mfg. Co., 61 F.3d 123, 128-29
2 (2d Cir. 1995).

3 In addition to the somewhat inconclusive evidence of Barr's
4 warfarin sodium pricing, plaintiffs presented evidence that the
5 exclusive dealing arrangement reduced the supply of clathrate
6 available to generic manufacturers. They offered evidence that
7 ACIC/Brantford's own production plans called for the production
8 of a greater amount of clathrate than Barr intended to purchase.
9 This output was effectively lost to the generic warfarin sodium
10 industry because of the exclusive terms of the contract. In
11 addition, for the reasons previously discussed, plaintiffs have
12 created a genuine issue of material fact regarding
13 ACIC/Brantford's market power in the clathrate market and Barr's
14 market power in the generic warfarin sodium market. Their
15 proffer is sufficient to satisfy their initial burden under the
16 rule of reason.

17 The burden then shifts to defendants to offer pro-
18 competitive justifications for the arrangement. Even if we
19 credit defendants' evidence, the essential facts are in dispute.
20 The period of 1995-98 was a period of uncertainty in an emerging
21 market. Supplies were difficult to procure, and the number of
22 actual or potential generic warfarin sodium manufacturers was
23 unknown, in part due to delays relating to FDA approval. This
24 was a time when it might make particular sense for a supplier to
25 secure a ready buyer and for a buyer to secure a steady supply of
26 materials. Were there other clathrate competitors available, a

1 point which is in dispute, this exclusive arrangement could have
2 significant pro-competitive benefits both to the signatories and
3 to competition overall.

4 The calculus of course changes if ACIC/Brantford was indeed
5 the sole available supplier, and the evidence suggests Barr and
6 ACIC/Brantford at least suspected that was the case. If so, then
7 an exclusive dealing agreement that dedicated all that supply to
8 one buyer could freeze out competition to an extent that greatly
9 outweighed any pro-competitive effects. At the least, such a
10 situation would heighten the need to consider if less restrictive
11 means could have achieved the pro-competitive benefits of an
12 exclusive dealing arrangement without totally foreclosing
13 competition.

14 The issue of duration which troubled us in considering § 2
15 is also relevant here: a transitory advantage does not
16 significantly harm competition and therefore should not violate
17 § 1, but plaintiffs have provided at least some evidence to
18 suggest that this was not a transitory advantage, but rather was
19 a substantial impediment to competition. For example,
20 Apothecon's general manager reported that even though its offer
21 price to the Eckerd and CVS drugstore chains was as much as 25
22 percent below Barr's, neither was willing to leave Barr after
23 having devoted substantial time to switching patients and getting
24 their pharmacists comfortable with the new product. The
25 assessment of long-term effects depends greatly on credibility of
26 the evidence, which is the task of the jury.

1 Once again, the district court resolved crucial factual
2 disputes against the non-moving party on a motion for summary
3 judgment. We think plaintiffs' evidence provides a prima facie
4 case of a § 1 violation, and the district court should not have
5 terminated the case on summary judgment.

6 V Clayton Act Section 7

7 We pass now to the claimed violation of the Clayton Act.
8 Section 7 of the Clayton Act prohibits mergers or acquisitions if
9 the effect "may be substantially to lessen competition, or to
10 tend to create a monopoly." 15 U.S.C. § 18 (2000). Prior to
11 1996, Apotex, which is owned indirectly by Dr. Sherman, had owned
12 75 percent of ACIC/Brantford. In 1996 Apotex purchased the
13 remaining 25 percent to become ACIC/Brantford's sole owner.
14 Plaintiffs claim the 1996 purchase tended to impede competition
15 and monopolize the warfarin sodium market in violation of § 7
16 because the acquisition enabled defendants to misuse
17 ACIC/Brantford's monopoly in the clathrate market to gain
18 competitive advantage in the warfarin sodium market. Due to the
19 various parent/subsidiary relationships connected to Apotex,
20 plaintiffs included as defendants to this claim Apotex, Dr.
21 Sherman, Apotex Holdings, Inc., Sherman Delaware, Inc. and Barr.

22 The district court dismissed the § 7 claim against all
23 entities except Apotex because it ruled that "the only entity
24 that may be held liable under § 7 is the acquirer, Apotex Inc."
25 201 F. Supp. 2d at 279. The district court gave no explanation
26 for why defendants Dr. Sherman, Apotex Holdings, Inc. and Sherman

1 Delaware, Inc., were not also potentially liable since the
2 Clayton Act by its terms applies to both "direct and indirect"
3 acquisitions, and the court had previously found that Dr.
4 Sherman, through several subsidiaries, owned 100 percent of
5 Apotex Holdings and 100 percent of Sherman Delaware, which
6 combined own 100 percent of Apotex. Aside from pointing out that
7 plaintiffs cited no cases that extend liability under § 7 beyond
8 the acquirer, the court offered no analysis of its own.

9 While we find sparse case law either supporting or rejecting
10 the district court's conclusion -- indeed only one case seems to
11 have addressed the question head on, see Cmty. Publishers, Inc.
12 v. Donrey Corp., 882 F. Supp. 138 (W.D. Ark. 1995) -- the Clayton
13 Act's application to "direct or indirect" acquisitions suggests
14 to us that parent/subsidiary relationships, or any other
15 corporate structure, ought not preclude application of the
16 Clayton Act § 7 to any entity that had an active role in an
17 acquisition that tends "substantially to lessen competition."
18 However, we need not decide in this case whether any defendant
19 that directly or indirectly owned Apotex played a sufficient role
20 to be held liable, for we hold that plaintiffs have failed to
21 demonstrate that the acquisition itself was likely to impair
22 competition.

23 Although § 7 of the Clayton Act targets restraint of trade
24 and monopolization, it is not co-extensive with the Sherman Act.
25 After § 7 was amended in 1950, the Supreme Court recognized that
26 § 7 was intended to be a pre-emptive tool that gave the Federal

1 Trade Commission and the courts the power to stop mergers that
2 "tended" to impair trade, even before the effects reached the
3 level of violating the Sherman Act. See Brown Shoe, 370 U.S. at
4 317; see also id. at 312-23 (surveying the history and purpose of
5 § 7 in light of the 1950 amendments). Section 7 therefore
6 provides for scrutiny of a transaction to evaluate if the
7 acquisition will tend to increase concentration of market power
8 and/or inhibit competition. See Copperweld, 467 U.S. at 777.
9 The Supreme Court also confirmed that the focus of § 7, like the
10 Sherman Act, is on competition not competitors. Brown Shoe, 370
11 U.S. at 320.

12 Plaintiffs' allegations as to the specific anti-competitive
13 effects of Apotex's purchase of ACIC/Brantford are meager indeed,
14 occupying but a single paragraph of their appellate brief. As
15 best we can glean, plaintiffs allege that Apotex, Dr. Sherman,
16 and the various subsidiaries were all passive investors in
17 ACIC/Brantford prior to 1996, but that their purchase in 1996 of
18 the remainder of ACIC/Brantford's shares enabled them to take
19 anti-competitive actions. According to plaintiffs, lack of a
20 minority shareholder meant that defendants were free to take
21 steps that were not in ACIC/Brantford's economic interests, such
22 as misleading Geneva and refusing to fill Geneva's order for
23 clathrate. Plaintiffs assert that these actions were a misuse of
24 ACIC/Brantford's monopoly in the clathrate market designed to
25 gain advantage in the generic warfarin sodium market.

1 Whatever the merits of this characterization of defendants'
2 motive and actions, the allegations are not of a sort that
3 implicates the Clayton Act. The Clayton Act is concerned with
4 whether an acquisition or merger itself may cause antitrust
5 injury. Cargill, Inc. v. Monfort of Colorado, Inc., 479 U.S.
6 104, 115-17 (1986). Plaintiffs themselves assert in other causes
7 of action that ACIC/Brantford had a monopoly on clathrate even
8 before Apotex purchased the remaining shares of ACIC/Brantford,
9 indicating that the acquisition itself had no effect on the
10 degree of concentration or competition in the clathrate market.
11 Further, the Barr/ACIC/Brantford exclusive dealing agreement,
12 which is the crux of the antitrust claims, was entered into
13 before the purchase of ACIC/Brantford.

14 Plaintiffs have alleged no potential antitrust harm stemming
15 from the acquisition, and thus, at most, allege that the purchase
16 gave ACIC/Brantford unity of ownership. The fact that the 1996
17 purchase removed a layer of internal corporate control is not by
18 itself a concern of the Clayton Act, for that removal standing
19 alone is not an antitrust violation.

20 Without directly saying so, plaintiffs appear to hint that
21 Dr. Sherman's connection with Barr -- he was a significant
22 shareholder and member of Barr's Board of Directors in 1996 --
23 should lead us to examine the vertical aspects of the
24 acquisition. The Supreme Court and this Court have set forth
25 standards for assessing if a vertical merger violates the Clayton
26 Act: "The primary vice of a vertical merger or other arrangement

1 tying a customer to a supplier is that, by foreclosing the
2 competitors of either party from a segment of the market
3 otherwise open to them, the arrangement may act as a "'clog on
4 competition' which 'deprive[s] . . . rivals of a fair opportunity
5 to compete.'" Brown Shoe, 370 U.S. at 324; United States v. Am.
6 Cyanamid Co., 719 F.2d 558, 566 (2d Cir. 1983). Plaintiffs' only
7 evidence that competitors were foreclosed or that there was a
8 clog on competition comes from the Barr/ACIC/Brantford exclusive
9 dealing agreement, not the 1996 acquisition itself.

10 All we really have before us is plaintiffs' sneaking
11 suspicion that something illegal occurred from the acquisition of
12 ACIC/Brantford. But plaintiffs have the burden to present
13 evidence that the purchase violated the Clayton Act. They cannot
14 on the basis of surmise and suspicion transform their Sherman Act
15 allegations into a Clayton Act violation. The district court's
16 dismissal of the Clayton Act claim should be affirmed.

17 VI Joint Venture

18 In the district court defendants challenged plaintiff
19 Apothecon's standing to raise its state law claims. Apothecon
20 and Geneva had asserted that they were joint venturers and that,
21 under New Jersey law, Apothecon could sue for injuries to the
22 joint venture. The district court ruled that Geneva and
23 Apothecon were not engaged in a joint venture and consequently
24 that Apothecon lacked standing to sue.

25 The trial court held the relationship lacked two crucial
26 elements to qualify as a joint venture: a joint property

1 interest in the subject of the venture and a sharing of losses.
2 It found that under the agreement between Apothecon and Geneva,
3 Geneva retained ownership of the finished tablets and then sold
4 them to Apothecon. Thus, it found no joint ownership in the
5 subject of the venture. The trial court also ruled that there
6 was no sharing of losses, but rather only a risk of losing an
7 initial capital investment. It ruled the possibility of losing
8 initial funds invested in the venture was not equivalent to
9 shared losses.

10 We turn first to the law. "A joint venture is a special
11 combination of two or more persons, whether corporate, individual
12 or otherwise, formed for some specific venture in which a profit
13 is jointly sought without the parties designating themselves as
14 an actual partnership or corporation." 12 Richard A. Lord,
15 Williston on Contracts, 36:9 at 644 (4th ed. 1999). Under New
16 Jersey law, which governs the plaintiffs' agreement, the elements
17 of a joint venture are essentially the same as of a partnership.
18 Carney v. Hansell, 831 A.2d 128, 134 (N.J. Super. Ct. App. Div.
19 2003). These elements "include agreement, sharing profits and
20 losses, ownership and control of the partnership's property and
21 business, community of power, rights upon dissolution and the
22 conduct of the parties towards third persons, among others." Am.
23 Fire & Cas. Ins. Co v. Manzo, 788 A.2d 925, 929 (N.J. Super. Ct.
24 App. Div. 2002). Joint venture status is created by contract,
25 express or implied, and depends on the mutual intent of the

1 parties. Sullivan v. Jefferson, Jefferson & Vaida, 400 A.2d 836,
2 839 (N.J. Super. Ct. App. Div. 1979).

3 We find the cases applying New Jersey law to be inconsistent
4 on the evaluation of joint venture status. Some cases hold, for
5 example, that sharing of profits and losses is required, while
6 others hold that sharing of profits or losses is sufficient.
7 See, e.g., Wittner v. Metzger, 178 A.2d 671, 675 (N.J. Super. Ct.
8 App. Div. 1962) (sharing of profits and losses required);
9 Hellenic Lines, Ltd. v. Commodities Bagging & Shipping, Process
10 Supply Co., 611 F. Supp. 665, 679 (D. N.J. 1985) (venturers must
11 share profits or losses); Ruta v. Werner, 63 A.2d 825 (N.J.
12 Super. Ct. Ch. Div. 1948) (finding a joint venture despite
13 agreement's lack of allocation of losses); Rodin Properties-Shore
14 Mall, N.V. v. Cushman & Wakefield, 49 F. Supp. 2d 728, 736-37 (D.
15 N.J. 1999) (lack of shared losses does not preclude finding of
16 joint venture); First Mechs. Bank v. Comm'r of Internal Revenue,
17 91 F.2d 275, 278 (3d Cir. 1937) (same).

18 Additional cases suggest that the absence of one or more
19 factors does not foreclose a finding of a joint venture. See,
20 e.g., Rodin, 49 F. Supp. 2d at 736 (unequal management
21 responsibilities does not preclude finding joint venture)
22 (quoting 46 Am. Jur. 2d Joint Ventures § 16 (1994) ("[A] joint
23 venture may exist although the parties have unequal control of
24 operations.")). Still other cases consider only some factors but
25 not others. See Upper Penns Neck Tp., Salem County v. Lower
26 Penns Neck Tp., Salem County, 89 A.2d 727, 732 (N.J. Super. Ct.

1 Law Div. 1952) (Joint venture requires an "agreement to enter
2 into an undertaking in the objects or purpose of which the
3 parties to the agreement have a community of interest and a
4 common purpose in its performance.").

5 After reviewing this inconsistent and sometimes conflicting
6 case law, we think on balance that the relationship between
7 Geneva and Apothecon contains sufficient indicia of a joint
8 venture to satisfy New Jersey law. Despite being styled a
9 "Development and Supply Agreement," it is clear that the contract
10 is more than a standard supply contract and in fact envisions a
11 substantial sharing of resources towards a joint enterprise.

12 We agree with the district court's point that the potential
13 for losing initial capital investments is not equivalent to
14 shared losses. Nevertheless, such potential loss points to a
15 mutual interest in success since both parties have an investment
16 at stake and each depends on the other to ensure they do not lose
17 that investment. The potential shared loss of investments, while
18 not itself sufficient evidence of a joint venture, still suggests
19 a fiduciary relationship towards each other and supports the
20 finding of a joint venture based on the other evidence.

21 Next, we consider the facts. We make six points in
22 developing our divergence from the trial court. First, a classic
23 element of a joint venture is that there is a limited objective
24 and scope of the venture. The Apothecon/Geneva agreement
25 specifically is limited to the development and distribution of
26 twelve pharmaceutical preparations specified in Appendix A to the

1 agreement. It is also limited in duration, having a fixed term
2 of five years with options for extension.

3 Second, the contract provides for significant sharing and
4 pooling of resources, skills and knowledge. In sections of the
5 agreement titled "Cooperation" and "Product Development," the
6 contract provides that the parties will share scientific and
7 medical information as well as pre-clinical and clinical data,
8 including "all toxicological, analytical, chemical data and the
9 like." The "Recitals" provisions outline the skills and
10 expertise that each party brings to the arrangement, a
11 consideration not usually relevant to a supply contract.

12 Third, there is a shared interest, although not strictly
13 speaking shared ownership, over the subject matter of the
14 venture. For example, Apothecon was responsible for funding
15 Geneva's research and development costs in the formulation,
16 testing, and development of the twelve products. Each party had
17 registration and filing responsibilities, Geneva with the FDA and
18 Apothecon with state medicaid agencies. The district court noted
19 that Geneva retained title to the drugs until it sold them to
20 Apothecon, but failed to note that Apothecon purchased the raw
21 materials used to manufacture the drugs. In sum, regardless the
22 state of title to the drugs at any given moment, the agreement
23 envisioned that both parties would be involved in the development
24 of the drugs and both had an ongoing interest in the endeavor.

25 Fourth, the contract provides for some degree of overlapping
26 control and management over the development. Each party had the

1 right to audit the books and records pertaining to the
2 development and sale of the products. Geneva was required to
3 permit Apothecon's representatives to visit and inspect its
4 facilities at any time. Apothecon had the right to audit Geneva
5 for compliance with the Current Good Manufacturing Practices
6 promulgated by the FDA. Geneva had the right to a quarterly
7 accounting from Apothecon detailing the quantity of goods sold,
8 total receipts, Apothecon's profit and loss on each product, and
9 the inventory on hand. This degree of mutual oversight suggests
10 to us a close relationship.

11 Fifth, there was a joint expectation of and participation in
12 profits. Geneva was to be paid a percentage of Apothecon's sales
13 of the drugs.

14 Sixth, plaintiffs presented some evidence that they held
15 themselves out as partners, for example by issuing advertisements
16 and launch packages that showed Apothecon and Geneva as partners.
17 There is also evidence that defendants recognized Geneva and
18 Apothecon were partners. ACIC/Brantford's Sergio Getrajdman for
19 example referred to Apothecon and Geneva as "partners on the
20 product," and Barr's chief operating officer, Paul M. Bisaro,
21 said Barr was aware of "the relationship between Apothecon,
22 Bristol-Myers and Invamed." Signs of a relationship are not
23 always signs of a joint venture, but the evidence is not
24 inconsistent with a finding of a joint venture.

25 We conclude that these aspects of the venture demonstrate
26 Geneva and Apothecon's mutual intent to engage in a joint

1 endeavor. More broadly, we are convinced that if there were
2 antitrust violations, Apothecon was likely injured by them and
3 should not be barred from seeking redress. While the district
4 court cannot be faulted for reaching a contrary conclusion given
5 the state of the case law, we nevertheless must reverse its
6 ruling that Apothecon lacks standing to sue. We hold instead
7 that Apothecon and Geneva were engaged in a joint venture under
8 New Jersey law and that Apothecon therefore has standing to
9 pursue claims as a plaintiff for injuries to the joint venture.

10 CONCLUSION

11 Accordingly, for the foregoing reasons, we (1) reverse the
12 grant of summary judgment dismissing all plaintiffs' claims
13 brought pursuant to the Sherman Act §§ 1 and 2; (2) affirm the
14 dismissal of the Clayton Act claim; and (3) reverse the ruling
15 that plaintiff Apothecon lacks standing to sue. The case is
16 remanded to the district court for further proceedings consistent
17 with this opinion.